



4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 130

[Docket No. FDA-1995-N-0062]

Food Standards; General Principles and Food Standards Modernization; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the proposed rule that appeared in the *Federal Register* of May 20, 2005. The proposed rule, entitled “Food Standards; General Principles and Food Standards Modernization,” would establish a set of general principles for food standards for FDA to use when considering whether to establish, revise, or eliminate a food standard. The proposed rule was issued jointly with the U.S. Department of Agriculture (USDA) and, while FDA will continue to engage with USDA regarding the proposed rule, we are extending the comment period to allow interested persons additional time to submit comments.

DATES: We are extending the comment period on the proposed rule that published in the **Federal Register** of May 20, 2005 (70 FR 29214). Submit either electronic or written comments by July 20, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 20, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until

11:59 p.m. Eastern Time at the end of July 20, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-1995-N-0062 for "General Principles and Food Standards Modernization; Reopening of the Comment Period." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469,

September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rumana Yasmeen, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-6060.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 20, 2005 (70 FR 29214), FDA and USDA jointly issued a proposed rule entitled “Food Standards; General Principles and Food Standards Modernization,” as a first step in instituting a process to modernize FDA definitions and standards of identity (and standards of quality and fill of container) consistent with section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), and USDA’s definitions and standards of identity or composition under the Federal Meat Inspection Act and the Poultry Products Inspection Act (21 U.S.C. 607(c) and 457(b)) (and standards of fill of container). The proposed rule, if finalized, would establish general principles that FDA and USDA would consider when determining whether to establish, revise, or eliminate a food standard.

Interested persons were originally given until August 18, 2005, to comment on the proposed rule. In the **Federal Register** of February 21, 2020 (85 FR 10107), we announced that we were reopening the comment period for an additional 60 days so that we could receive new

data, information, or further comments only on FDA-specific aspects of the proposed rule, including 13 general principles which we would consider when establishing, revising, or eliminating a food standard. The reopened comment period was scheduled to end on April 21, 2020.

We have received requests for an extension of the comment period for the proposed rule, which conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 90 days, until July 20, 2020. We believe that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: April 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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